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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,679	09/26/2003	Juan F. Granada	94510-010200/US	9812
35893 7590 07/10/2007 GREENBERG TRAUIG, LLP ONE INTERNATIONAL PLACE, 20th FL ATTN: PATENT ADMINISTRATOR BOSTON, MA 02110			EXAMINER GHERBI, SUZETTE JAIME J	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 07/10/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/672,679

Applicant(s)

GRANADA ET AL.

Examiner

Suzette J. Gherbi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15, 78-95, 105-111 and 113-175 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15, 78-95, 105-111, 113-134, 136-156, 160-175 is/are rejected.
- 7) ☐ Claim(s) 14, 135 and 157-159 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

1. Applicant's amendment dated 3/16/07 has been received in application serial number 10/672,679. All comments have been taken into consideration. Claims 16-77, 96-104, 112 have been canceled.

### ***Response to Arguments***

Applicant's remarks, filed 3/16/07, with respect to the rejection(s) of claim(s) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further search and consideration, a new ground(s) of rejection is made in view of Whitbourne et al. 2002/0018795 in view of Helmus et al. 6,730,313.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 15, 78-79, 93-95, 105-111, 113-120, 125-134, 136-144, 150-156, 160-167, 172-173 are rejected under 35 U.S.C. 103(a) as being unpatentable over

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Whitbourne et al. 2002/0018795 in view of Helmus 6,730,313. Whitbourne et al. discloses the invention as claimed comprising:

A biocompatible drug release matrix for a medical device comprising: a biocompatible polymer matrix; and a drug incorporated into the biocompatible polymer matrix, wherein the biocompatible polymer matrix is co-solubilized with the drug in a solvent to form a solution and the solvent is evaporated from the solution see [0065 example 3];

wherein the drug has antibiotic properties and anti-proliferative properties see section [0059];

wherein the drug is an analogue related to the quinone-containing alkylating agents of a mitomycin family; the biocompatible drug release matrix of claim 1 wherein the drug is mitomycin C (see [0059];

wherein a ratio of the weight of the biocompatible polymer matrix and the drug is *about* 4 to about 1, see section [0026]);

wherein the solvent is selected from the group consisting of water, saline, tetrahydrofuran, methanol, acetone, butyl acetate, cyclohexane, carbon tetrachloride, ether, chloroform, benzene, ethanol, toluene, dimethyl sulfoxide, petroleum ethers, other hydrocarbons and other organic solvents see section [0052];

wherein the biocompatible polymer matrix comprises polyvinyl pyrrolidone with an at least one isocyanate;

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wherein the biocompatible polymer matrix comprises a mixture of hydrophilic and hydrophobic polymers selected from the group consisting of polyurethanes, polyvinyl pyrrolidone, poly methyl methacrylate (PMMA), hydroxyethyl methacrylate and cellulose esters;

wherein the biocompatible polymer matrix comprises an erodible polymer ;

wherein the erodible polymer is selected from the group consisting of polyactide, polyactide with glycolide, polyesteramides, polyurethanes, poly(ethylene-urethane), poly(ester-urethane) and poly(ether-polyester-urethane), amino-acid based polyurethanes, polycaprolactone based polyurethanes, polyurethanes synthesized from poly(butylene succinate) polyol, poly(ethylene glycol), and 4,4'-methylenebis(cyclohexyl isocyanate), fat, carbohydrates and protein compounds.

However Whitboure does not specify that the drug forms a plurality of small particles in the solution. Helmus et al. teaches a drug release matrix suitable of medical devices (se 21:41-61) wherein drugs (either soluble or dispersed as fine particles) are formed in the solution and the solvent is evaporated from the solution. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a drug that forms particles in the solution as taught by Helmus et al. because the particle size of the drug can help to design the rate that the drug is released into the surrounding tissue.

Claims 11-13, 80-92, 119, 121-124, 145-148, 168-170, 174-175 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. in view of Helmus et al. and further in view of Rypacek et al. 7,160,592. Whitbourne et al. and Helmus have been disclosed supra and while Whitbourn et al. does teach that the polymer matrix incorporated with a drug may be applied to a substrate or scaffold they do not specifically state that it is for a vascular prosthesis or the specify rates of release of the drugs. Rypacek et al. 7,160,592 teach a polymer matrix which is also co-soulubiized with a drug and evaporated in a solvent solution. See col. 3, lines 62-67 4, lines 1-42; and col. 27, lines 25-33 col. 30, lines 26-47 and "burst time' col. 29,lines 61-67. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the medical device application of Whitbourne et al. and incorporate the time released properties as claimed and shown by Rypacek in order to custom tailor the prosthesis to immediate and lasting therapies to the site of implantation.

***Allowable Subject Matter***

Claims 14, 135, 157-159 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J-J Gherbi whose work schedule is Maxi-Flex off every other Friday and whose telephone number is 571-272-4751.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
SUZETTE GHERBI  
PRIMARY EXAMINER  
TECHNOLOGY CENTER 3700

12 June 13, 2007